

- (i) the first level is similar or different from a baseline level determined in a control population of patients unaffected by the lysosomal storage disorder;
- (ii) the first level is an indicator of presence or extent of the lysosomal storage disorder in the patient;
- (iii) the first saposin comprises saposin A, saposin B, saposin C, saposin D, prosaposin, mRNA encoding prosaposin, or a combination thereof; and
- (iv) the first sample is a plasma, serum, whole blood, urine, or amniotic fluid sample.
2. (Amended) The method of claim 1, wherein the first tissue sample is a plasma sample.
3. (Amended) The method of claim 1, wherein the first tissue sample is a whole blood sample.
4. (Amended) The method of claim 1, wherein a presence of the lysosomal disorder in the patient, is indicated by the measured first level exceeding the baseline level. a mean level in a control population of individuals not having a the lysosomal storage disorder, to indicate presence of the disorder in the patient.
5. (Amended) The method of claim 1, further comprising:
measuring the a second level of the at least one saposin in a second tissue sample from the patient, the first and second samples being obtained at different times; and
comparing the first level and the second level levels in the samples to indicate monitor progression of the disease,
wherein,
(i) the second saposin comprises saposin A, saposin B, saposin C, saposin D prosaposin, mRNA encoding prosaposin, or a combination thereof;
(ii) the comparison of the first level and the second is an indicator of the progression of the disease in the patient; and
(iii) the second sample is a plasma, serum, whole blood, urine, or amniotic fluid sample.
6. (Original) The method of claim 1, wherein the patient is undergoing treatment for the lysosomal storage disorder.

7. (Amended) The method of claim 4, wherein the measured level is greater than the 95% 95th percentile level in the control population.
8. (Original) The method of claim 1, wherein the patient is not known to have a lysosomal storage disorder before the measuring step.
9. (Original) The method of claim 1, wherein the patient is an infant less than one year old.
10. (Original) The method of claim 1, wherein the patient is a fetus and the sample is a fetal blood sample.
11. (Amended) The method of claim 1, wherein a change in the first level of the saposin indicates progression or regression of the disorder in the patient that is known to have a lysosomal storage disorder. wherein the patient is known to have a lysosomal storage disorder and the level of the saposin indicates progression of the disorder.
12. (Amended) The method of claim 1, wherein a change in the first level of the saposin indicates a response to treatment of the lysosomal storage disorder in the patient that being treated for the lysosomal storage disorder. wherein the patient is known to have a lysosomal storage disorder, and is being treated for the disorder, and the level of the saposin indicates response to treatment.
13. (Amended) The method of claim 1, wherein the first saposin or second saposin is selected from the group consisting of saposin A, saposin B, saposin C, and saposin D, prosaposin, and mRNA encoding prosaposin, and a combination thereof.
14. (Amended) The method of claim 1, wherein the saposin is selected from the group consisting of saposin A, saposin C, or saposin D.
15. (Amended) The method of claim 1, wherein the measuring step ~~comprising~~ comprises detecting binding between a saposin polypeptide and an antibody.
16. (Original) The method of claim 15, wherein the antibody is a monoclonal antibody.
17. (Original) The method of claim 15, wherein the antibody is immobilized to a solid phase.

18. (Amended) The method of claim 1, wherein the lysosomal storage disorder ~~order~~ is selected from the group consisting of cystinosis, Fabry's disease, Niemann-Pick disease, Pompe's disease, and Wolman disease, and a combination thereof.
19. (Original) The method of claim 1, further comprising informing the patient or a parent or guardian thereof of the presence of the lysosomal storage disorder.
20. (Amended) The method of claim 1, further comprising determining a treatment program based on the measurement of the first level of the first saposin.
21. (Withdrawn From Consideration)
22. (Withdrawn From Consideration)
23. (Withdrawn From Consideration)
24. (Withdrawn From Consideration)
25. (Withdrawn From Consideration)
26. (Withdrawn From Consideration)
27. (Withdrawn From Consideration)
28. (Withdrawn From Consideration).
29. (Withdrawn From Consideration)
30. (Withdrawn From Consideration)
31. (Withdrawn From Consideration)
32. (Withdrawn From Consideration)
33. (Withdrawn From Consideration)
34. (Withdrawn From Consideration)

35. (Withdrawn From Consideration)

36. (Amended) A method of monitoring treatment of a lysosomal storage disease in a patient, comprising:

determining a pre-treatment baseline level of a saposin in a tissue sample from the patient with a lysosomal storage disorder before treatment with an agent;

determining a post-treatment baseline level of the saposin in a sample from the patient with the lysosomal storage disorder after treatment with the agent; and

comparing a the pre-treatment baseline level of the saposin in a tissue sample ~~from the patient obtained after treatment with the agent; agent with the baseline level, and with~~ the post-treatment baseline level of the saposin, wherein

(i) the sample is a plasma, serum, whole blood, urine, amniotic fluid sample, or a mixture of:

(ii) saposin is selected from the group consisting of saposin A, saposin B, saposin C, saposin D, prosaposin, mRNA encoding prosaposin, and a combination thereof; and

(iii) a reduction in the post-treatment baseline level after treatment relative to the pre-treatment baseline level indicates a positive treatment outcome.

37. (Withdrawn From Consideration)

38. (Withdrawn From Consideration)